



Food and Drug Administration
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Biomet Manufacturing Corporation
Mr. Dean Heit
Senior Regulatory Affairs Specialist
Biomet UK Ltd.
Waterton Industrial Estate
Bridgend, Mid Glam, CF31 3XA
UK

December 29, 2014

Re: K142746

Trade/Device Name: G7™ Finned Acetabular Shell

Regulation Number: 21 CFR 888.3358

Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis

Regulatory Class: Class II

Product Code: LPH, LZO, OQG, KWZ, JDI, OQH, OQI, PBI

Dated: December 2, 2014

Received: December 4, 2014

Dear Mr. Heit:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K142746

Device Name

G7™ Finned Acetabular Shell

Indications for Use (Describe)

1. Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Correction of functional deformity.
4. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques.
5. Revision procedures where other treatment or devices have failed.

Porous acetabular shells and femoral stems are indicated for uncemented biological fixation. Non-coated or polyethylene components may be used with mating components that are indicated for either cemented or uncemented use.

Indications for Biomet G7 Freedom Constrained Liners:

The Biomet G7 Freedom Constrained Liner is indicated for use as a component of a total hip prosthesis in primary and revision patients at high risk of dislocation due to a history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease, or intraoperative instability, and for whom all other options to constrained acetabular components have been considered.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the G7™ Finned Acetabular Shell 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on August 12, 2005.

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Contact: Dean Heit
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Date: December 2, 2014

Subject Device: Trade Name: G7™ Finned Acetabular Shell
Common Name: Acetabular Shells

Classification Name: LPH – Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis (21 CFR 888.3358)

Other Applicable Product Codes:

LZO – Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis. (21 CFR 888.3353)

OQG – Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis. (21 CFR 888.3358)

KWZ – Hip joint metal/polymer constrained cemented or uncemented prosthesis (21 CFR 888.3310)

JDI – Hip joint metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3350)

OQH – Hip joint metal/polymer semi-constrained cemented prosthesis. (21 CFR 888.3350)

OQI – Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR 888.3353)

PBI – Hip joint metal/polymer constrained cemented or uncemented prosthesis. (21 CFR 888.3310)

Legally marketed devices to which substantial equivalence is claimed:

- G7™ PPS Acetabular Shell – Part of G7™ Acetabular System K121874 (Biomet)
- Mallory-Head Acetabular Shell – part of Mallory-Head Hip System K921181 (Biomet)

Device Description

The G7™ Finned Acetabular Shell is a medical device intended to be used as part of a hip joint replacement in Total Hip Arthroplasty procedure by qualified surgeons in the field of orthopaedics. The G7™ Finned Acetabular Shell is utilized to replace the acetabulum, and will be used in conjunction with the existing G7 Acetabular Cup bearing system (K121874), instruments and modular femoral system. The G7™ Finned Acetabular Shell will have the same internal geometry, liner locking system and PPS coating as the G7 Acetabular Cup System Shells (K121874) but will feature fins to provide improved primary fixation and anti-rotational stability.

Intended Use and Indications for Use

1. Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Correction of functional deformity.
4. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques.
5. Revision procedures where other treatment or devices have failed.

Porous acetabular shells and femoral stems are indicated for uncemented biological fixation. Non-coated or polyethylene components may be used with mating components that are indicated for either cemented or uncemented use.

Indications for Biomet G7 Freedom Constrained Liners:

The Biomet G7 Freedom Constrained Liner is indicated for use as a component of a total hip prosthesis in primary and revision patients at high risk of dislocation due to a history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease, or intraoperative instability, and for whom all other options to constrained acetabular components have been considered.

Summary of Technological Characteristics

The rationale for substantial equivalence is based on consideration of the following characteristics:

- **Intended Use:** The G7™ Finned Acetabular Shell for Primary and Revision Total Hip Arthroplasty.
- **Indications for Use:** Indications for use are given above and the same indication for use as the predicate devices.

- **Materials:** Ti4Al6V alloy compliant to ISO 5832-3:2012 & ASTM F136 and are the same material as the predicate devices.
- **Design Features:** The design features are the same as the predicate devices but will feature fins to provide improved primary fixation and anti-rotational stability
- **Sterilization:** The sterilization is identical to the predicate devices and are Gamma irradiated. 25-40kGy Sterility Assurance Level: 10^{-6}

Summary of Performance Data (Nonclinical and/or Clinical)

- Non-Clinical Tests
 - Push-In testing of Acetabular Shell.
 - Torque-out testing of Acetabular Shell.
 - Deformation testing of Acetabular Shell
 - Comparison fatigue testing with Predicate device (Finite Element Analysis)
 - Comparison with Predicate device (Tolerance Analysis)
- Clinical Tests
 - None provided as a basis for substantial equivalence

Substantial Equivalence Conclusion

The proposed G7™ Finned Acetabular Shell has the same intended use and indications for use as the predicate devices. The proposed device has similar technological characteristics to the predicates, and the information provided herein demonstrates that:

- any differences do not raise new questions of safety and effectiveness; and
- the proposed device is at least as safe and effective as the legally marketed predicate device.